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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,538

03/11/2004

Srinka Ghosh

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AGILENT TECHNOLOGIES, INC.
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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

05/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,538	Applicant(s) GHOSH, SRINKA	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on 28 January 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner has approved of reopening prosecution by signing below.

Applicant is reminded that professional conduct is to be maintained in response to all communications from the office.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. *This is a new grounds of rejection.*

Claims 1 and 12 are drawn to a method for detecting a background intensity gradient or characterizing background intensity gradients within a microarray data set comprising computing convergence metrics and determining a background intensity gradient. The instant method comprises steps that do not include a physical transformation of matter.

As such and as emphasized by the New Interim Guidelines, the claims will be evaluated for providing a practical application. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter.

Therefore, the claims must be evaluated for providing a practical application that produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case, claims 1 and 12 recite “outputting a numerical indication of the determined background intensity gradient to at least one of: a user, a display, a memory, or a computer”. The recitation of “outputting...to a memory or a computer” renders the claim non-statutory, as outputting to a memory or computer is not a tangible result, as the “output” could merely reside *in silico* and never be accessible, for example, to a user. Therefore these claim embodiments are non-statutory.

Claims 11, 19 and 20 are drawn to a computer program and an analysis system for detecting a background intensity gradient within a microarray data set. In the instant claims the

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“program stored in a computer readable medium” (claims 11 and 19) or an “analysis system” (claim 20), constitute nonfunctional descriptive material, as no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e. abstract ideas, stored in a computer-readable medium, in a computer, does not make the claims statutory. Further, data structures, as in a “program” are descriptive material, *per se* and are not statutory because they are not capable of causing a functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). Computer programs are viewed as computer listings, *per se*, i.e., the description or expression of the programs, are not physical things. They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and the other claimed elements of a computer that permit that computer program’s functionality to be realized. In the instant case, the “outputting to a memory or computer” does not render the claims statutory, as these embodiments fail to provide a tangible result, as indicated above.

It is noted that “outputting to a user or a display” is statutory.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

§ 2172.01. The omitted elements are: the relationship, in claim 1, between steps (1) drawn to computing convergence metrics for features within the microarray data set and step (2) drawn to determining that the microarray data set exhibits a background intensity gradient. Step (1) computes convergence metrics and when they are larger than a threshold value, somehow determines that the microarray data set exhibits a background intensity without any steps in which to “determine” the exhibition of a background intensity. *This is a new grounds of rejection.*

The instant specification discloses that:

“in general, the intensity associated with a pixel in the image of a microarray is the sum of: (1) a signal-intensity component produced, at a location of the surface of the microarray corresponding to the pixel, by bound target molecules; and (2) a background-intensity component produced by a wide variety of background-intensity-producing sources, including noise produced by electronic and optical components of a microarray scanner, general non-specific reflection of light from the surface of the microarray during scanning, or, in the ease of radio-labeled target molecules, natural sources of background radiation, and various defects and contaminants on, and damage associated with, the surface of the microarray. A wide variety of different computational techniques are employed to determine the background-intensity components of pixel intensities and to subtract the background-intensity components from measured pixel intensities in order to recover the signal-intensity components. Unfortunately, it may be difficult to precisely determine the background intensity components of pixels in an image of a microarray, particularly when the microarray contains contaminants and/or defects that produce background intensity gradients within the image of the microarray. For this reason, designers, manufacturers, and users of microarrays and microarray scanners continue to seek improved and computationally efficient methods for detecting defects and damage reflected in background intensity gradients in images of microarrays (page 5, lines 23-30 to page 6, lines 1-11)”.

The specification further teaches that:

“the background intensity is expected to be relatively uniformly distributed within the image of a microarray, and have a variance and average magnitude characteristic for the type of microarray, experimental procedure, and microarray scanner used to scan the microarray. In processing microarray data, the background-intensity component is generally estimated, by any of various computational techniques, and subtracted from the measured intensity to produce an estimated signal intensity. However, in reality, the background intensity components associated with pixels in the image of a microarray may be quite non-uniformly distributed. Non-uniform distributions of background-pixel intensities across the image of a microarray may result from background intensity gradients within the image of a microarray” (page 13, lines 1-9).

The specification proposes that the instant invention provide an efficient method for determining features in a microarray in that:

“a convergence metric is computed for a feature by determining the size of a region surrounding the feature for which the difference between the mean and median pixel intensities is large. Features with computed metrics of large magnitudes are generally found in, or adjacent to, regions within the image of the microarray with steep background intensity gradients. The presence of features with computed metrics of large magnitudes may be used in one or more embodiments as an indication of the presence of background intensity gradients within the image of the microarray, and the patterns of distribution of such features within an array of features may be used to provide an indication of the location and directions of background intensity gradients within the image of the microarray (page 6, lines 16-27)”.

In order to perform the instant method of determining whether or not a microarray data set exhibits a background intensity gradient after computing a convergence metric it is essential that the presence of features that have large computed metrics are used to determine a background intensity gradient within the microarray. However, the instant claims are missing the computation step of actually using the metric in the determination of the background

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intensity gradient. Without such a step in the claims, essential elements for operation are omitted.

Conclusion

No claims are allowed.

The outstanding rejections under 35 USC 112, 1st paragraph pertaining to NEW MATTER are hereby withdrawn. It is noted that there is support for the claim limitations of "outputting to a user, a display, a memory or a computer" at least at pages 11 and 12 of the instant Specification.

The outstanding rejections under 35 USC 103 (a) have been withdrawn after further consideration of the prior art of record.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Lori A. Clow, Ph.D./

Primary Examiner, Art Unit 1631

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/798,538	GHOSH, SRINKA	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	